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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/097,023	06/12/1998	JILL MCFADDEN	290252021800	2472

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EXAMINER

THOMPSON, MICHAEL M

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 02/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/097,023

Applicant(s)

MCFADDEN ET AL.

Examiner

Michael M. Thompson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 November 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15, 17-22, 24-42, 44-48, 50-56, 58 and 59 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

- 6) ☒ Claim(s) 1-15, 17-22, 24-42, 44-48, 50-56, 58-59 is/are rejected.

- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

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## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1-9, 13-15, 17-22, 24-27, 31-37, 40-42, 44-48, 50-56, and 58-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Samson (5,702,373) in view of Cook (4,637,396). Samson discloses a catheter comprising an elongated tubular member having a proximal end, distal end, and a passageway defining a lumen extending between the proximal and distal ends, said elongate tubular member comprising a braid and an inner tubular liner in coaxial relationship with the braided tubular member. Samson further discloses and outer cover; a braided tubular member formed from metal wire; a relatively stiff proximal segment and relatively flexible distal segment; a braided tubular member comprised of a metal alloy/stainless steel having a generally circular cross-sectional shape; wherein at least one of the inner tubular

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liner and the outer tubular cover are radiopaque; a braided tubular member that is generally not radially expandable; an inner proximal liner and an outer proximal cover; a braid interposed between the inner proximal liner and the outer proximal cover; a braided tubular member extending into the proximal segment. More specifically, Samson discloses a braided tubular member comprising of super elastic alloy (col. 7, line 64), nickel-titanium alloy (col. 8, lines 10-12), nitinol (col. 8, lines 10-12), platinum alloy (col. 12, lines 10-12); wherein the wire has a diameter of about 0.3 mil- 1.5 mil (col. 11, lines 60-62); comprising a first strand made from a first material and a second made from a second material; an outer tubular cover comprised of polyethylene (col. 10, line 36), polyvinyl chloride (col. 10, line 49); and an inner tubular liner comprised of polyethylene (col. 10, line 27), PVC (col. 10, line 27), EVA (col. 10, line 28), PET (col. 10, line 28); and a coil (282) interposed between the inner proximal liner and the outer proximal cover. Samson teaches all of the limitations of the claims with the exception of a knit tubular member. Cook teaches a catheter with a knitted reinforcement member. It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to simply modify the braided reinforcement layer of Samson with the knitted reinforcement member taught by Cook for the well known purpose of reinforcement of a device for the well known purpose of adding rigidity along certain portions of a catheter body and/or help prevent undesirable characteristics during usage such as kinking of the catheter tube in a medical procedure. Please note that it is also the Examiner's position that both braided and knitted reinforcement structures are recognized in the art as equivalents for their use in the catheter art and the selection of any of these known equivalents to reinforce a catheter would be within the level of ordinary skill in the art.

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4. Claims 10-12, 28-30, and 38-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Samson ('373) in view of Cook ('396) as applied to claims 1-9, 13-27, 31-37, and 40-60 above, and further in view of Samson et al., U.S. Patent 5,549,109. Samson ('373) in view of Cook teaches all of the elements of Applicant's claims with the exception of a knit tubular member comprised of a multi-filament wire. Samson et al. ('109) discloses multi-filament tubes (302) that are woven (col. 9, lines 65-67). It would have been obvious to one having ordinary skill in the art to modify the modified catheter of Samson ('373) and Cook to use a multi-filament wire as taught by Samson ('109) to improve kinking resistance. Samson discloses the use of stainless steel, platinum, and nitinol as the material for the multi-filament wire to improve or simply change kinking resistance and further to provide different flexibility characteristic.

#### ***Response to Arguments***

5. Applicant's arguments filed 11/27/02 have been fully considered but they are not persuasive. The Examiner respectfully traverses Applicant's arguments with respect to the characterization of the Cook reference. Applicant has stated that the Cook reference "appears to merely suggest a braided section for preventing over-expansion of an inflatable balloon." In general, the Examiner agrees with Applicant's assertion that the Cook reference teaches a *knitted* member for reinforcement of the balloon structure. However, it is the Examiner's position that the knitted member taught by Cook is not necessarily expandable. Applicant further suggests that there is no motivation to combine the references and the proposed modification would render the prior art invention being modified unsatisfactory. Applicant recites that "If the knitted fabric tubular member of Cook were given the characteristics called for by Samson, the balloon

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would not be capable of expanding and would be unsatisfactory for its intended purpose.” It should be noted that the Examiner is only relying upon the knitted member of Cook to modify the Samson device. However, the Examiner is still unclear as to how Applicant has interpreted the knitted member taught by Cook within the confines of his argument. Is Applicant suggesting that the knitted portion of the Cook reference is expandable from a relatively tight fitting knitted member, when the balloon is in the deflated position, to an expanded state thereby conferring some level of elasticity in the knitted member? While this is not taught by the Cook reference, it is the Examiner’s position that it still fails to render the combination improper. In the least, the knitted portion taught by Cook is constructed such that when the balloon is in the deflated position the knitted portion is sufficiently “deflated” or firmly supporting the balloon and catheter as depicted in the Figures. Similarly, when modified to support the device taught by Samson, it is anticipated that the knitted portion will accommodate the catheter of Samson in a similar manner. It is important to note that the recitation of a braided or knitted member that is “generally not radially expandable” does not preclude it from some radial expansion. Regardless, it is the Examiner’s position that the Samson device does not structurally comprise an expandable member and therefore when modified by the knitted member of Cook there is no radial expansion.

In addressing Applicant’s arguments with respect to the Examiner’s motivation for combination, it is the Examiners position that whether or not Cook intended to reinforce his balloon when adding the knitted reinforcement to prevent kinking is not germane to the issue of motivation in combining references in the instant application. As Applicant is aware, MPEP § 706.02(j) clearly states that, “To establish a prima facie case of obviousness,.... First, there must

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be some suggestion or motivation, *either* in the references themselves *or in the knowledge generally available to one of ordinary skill in the art*, to modify the reference or to combine reference teachings....” It is the Examiner’s position that knitted members used for reinforcement to prevent kinking or to inherently add rigidity is knowledge generally available to one of ordinary skill in the art. In light of Examiner’s arguments *supra*, the Examiner has further sustained the rejection of claims 10-12, 28-30, and 38-39.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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*Contacts*

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Michael Thompson whose telephone number is (703) 305-1619. The Examiner can normally be reached on Monday through Friday from 9 am to 5 PM.

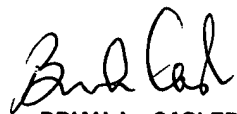
If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Primary, AnhTuan Nguyen, can be reached on (703) 308-2154. The official fax phone number for submissions to the organization where this application or proceeding is assigned is (703) 872-9302. The official fax phone number for submission of After Final response is (703) 872-9303.

Michael M. Thompson

Patent Examiner

MT 

February 7, 2003

  
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